4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

The Food and Drug Administration/European Medicines Agency Orphan Product Designation and Grant Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration's (FDA) Office of Orphan Products Development is announcing the following meeting entitled "The Food and Drug Administration/European Medicines Agency Orphan Product Designation and Grant Workshop." This 1-day workshop is intended to provide valuable information about the FDA and European Medicines Agency (EMA) Orphan Drug Designation programs, the FDA Humanitarian Use Device (HUD) Designation program, and the FDA Orphan Products Grant program to participants representing pharmaceutical, biotechnology, and device companies, as well as academics.

Date and Time: The meeting will be held on October 4, 2013, from 8:30 a.m. to 4 p.m.

Location: The meeting will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

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Registration: Interested participants may register for this meeting at the following Web site: https://events-support.com/events/FDA_Orphan_Workshop. If you need sign language interpretation during this meeting, please contact Eleanor Dixon-Terry at Eleanor.Dixon-Terry@fda.hhs.gov by September 20, 2013.

Attendance: Online registration for the workshop will be limited to 240 participants for the morning session, of which approximately 50 teams (up to 150 participants) may register for the one-on-one sessions. There will be no registration fee for the workshop.

For participants who cannot attend the morning meetings, simultaneous live interactive Webcasts will be made available. Participants may access the drug and biologics Webcast by visiting the following site: https://collaboration.fda.gov/odd100413/. The medical devices Webcast can be accessed by visiting: https://collaboration.fda.gov/hudd100413/.

SUPPLEMENTARY INFORMATION:

The FDA/EMA Orphan Product Designation and Grant Workshop is being conducted in partnership with the European Organisation for Rare Diseases, Genetic Alliance, and the National Organization for Rare Disorders.

The morning program includes two simultaneous sessions. The first will provide an overview of the FDA and EMA Orphan Drug Designation programs, respectively, while the second will provide an overview of the FDA HUD Designation Program and Pediatric Device Consortia Grant Program. Both morning sessions will also cover the Orphan Products Grant

Program as they relate to drugs, biologics, and devices. Both of these morning sessions will also be available by Webcast.

The afternoon session (no Webcast), provides an opportunity for appropriately registered participants to have one-on-one meetings with FDA staff members onsite, to discuss the specifics on how to apply for an orphan product grant, a HUD designation, or orphan drug designation. It also provides for videoconference sessions with EMA staff representatives on EMA orphan drug designation. Participants requesting one-on-one meetings are expected to bring information for at least one candidate orphan drug or device that holds promise for the treatment of a rare disease or condition in order to discuss the processes for putting together an application. In addition, participants in the HUD or orphan drug designation one-on-one sessions are highly encouraged to come prepared with a working draft submission of their particular promising therapy in order to maximize the utility of the one-on-one meetings.

Dated: August 16, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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